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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/604,876	06/28/2000	Mercy M. Davidson	0575/56614/JPW/JML/HA	6365

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Cooper & Dunham LLP  
1185 Avenue of the Americas  
New York, NY 10036

EXAMINER

SCHNIZER, RICHARD A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 11/20/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/604,876

Applicant(s)  
Davidson

Examiner  
Richard Schnizer

Art Unit  
1635



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 21, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5, 8-10, and 12-19 is/are pending in the application.
- 4a) Of the above, claim(s) 13-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 8-10, and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

The Examiner and art unit associated with this application have changed. Please direct further correspondence to Richard Schnizer, Art Unit 1635.

An amendment was received and entered as Paper No. 8 on 8/21/02. Claims 2, 6, 7, and 11 were canceled.

Claims 1, 3-5, 8-10, and 12-18 remain pending in the application. Claims 13-18 were withdrawn from consideration in Paper No. 7 as being drawn to a non-elected invention.

Applicant timely traversed the restriction requirement which was subsequently made final.

Claims 1, 3-5, 8-10 and 12 are under consideration in this Office Action.

### ***Specification***

The specification is objected to because it identifies DMEM F12 as "Dubeco's minor essential medium" at page 17, line 9. DMEM F12 is Dulbecco's modified Eagle medium.

### ***Claim Objections***

Claims 8-10 and 12 are objected to because they are ungrammatical. Addition of the word "to" immediately after the word "due" in step (b)(ii) of claim 8 is suggested.

### ***Claim Rejections - 35 USC § 112***

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Claims 8-10, and 12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 8-10 and 12 require a fibroblast cell line subject to growth selection due [to] incapacity to perform glycolysis. The claims appear to require that the incapacity to perform glycolysis is due to depletion of mitochondrial DNA from the fibroblasts. However, one of ordinary skill in the art appreciates that the biochemical apparatus for performing glycolysis is located in the cytoplasm, not in the mitochondria, and that depletion of mitochondria does not affect the ability to perform glycolysis. In fact, it results in cells that must perform glycolysis in order to survive. See for example, King et al (Science 246: 500-503, 1989, of record) page 500, lines 12-17 of paragraph bridging columns 1 and 2. It follows that one cannot render a cell incapable of glycolysis by depleting its mitochondria, and for this reason one of skill in the art could not practice the invention as claimed without undue experimentation.

This rejection may be overcome by deleting the phrase "thereby rendering the fibroblast cell line subject to growth selection due incapacity to perform glycolysis". Alternatively the rejection may be overcome by amending the claims to make it clear that depletion of mitochondria renders the fibroblasts incapable of growth under conditions that prevent glycolysis.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (In Vitro Cellular and Developmental Biology 27(1): 63-74, 1/1991).

Wang teaches a human fetal cardiac myocyte cell line designated W1. This line is considered to be immortalized because it was maintained in culture for one year. See abstract. Claims 3-5 are included in the rejection because there is no apparent difference between these cells and the W1 line. For example, like the cells of claims 3-5, the W1 cells carry an expression construct encoding SV40 T antigen (pRSVTA<sub>g</sub>). See page 67, column 2, last complete sentence. The specification teaches that the cells of claims 3-5 express beta-myosin heavy chain, connexin43, and desmin. Wang is silent as to whether or not the W1 cells express these markers. However, expression of these proteins is considered to be an inherent characteristic of cardiomyocytes, and is therefore considered to occur in the W1 cells absent evidence to the contrary. The Office does not have the facilities for examining and comparing Applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed

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products are functionally different than those taught by the prior art and to establish patentable differences. See Ex parte Phillips, 28 USPQ 1302, 1303 (BPAI 1993), In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ2d 1922, 1923 (BPAI 1989).

### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 703-306-5441. The examiner can normally be reached Monday through Friday between the hours of 6:20 AM and 3:50 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader, can be reached at 703-308-0447. The FAX numbers for art unit 1632 are 703-308-4242, and 703-305-3014. Additionally correspondence can be transmitted to the following RIGHTFAX numbers: 703-872-9306 for correspondence before final rejection, and 703-872-9307 for correspondence after final rejection.

Inquiries of a general nature or relating to the status of the application should be directed to the Patent Analyst Trina Turner whose telephone number is 703-305-3413.

Richard Schnizer, Ph.D.

  
JAMES KETTER  
PRIMARY EXAMINER